

Reshaping Chemicals Policy on Two Sides of the Atlantic:

Ecosystem Impacts of Current Approaches and the Promise of Improved Sustainability through International Collaboration

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Abstract

The chemical industry is linked to some of the largest causes of biodiversity loss, including (1) pollution of soil, air, fresh water and oceans, (2) global climate change (3) urbanization and changing consumption patterns, (4) technological development, construction and mining, and (5) resource-intensive agricultural practices. Over the next 25 years, as global chemical production doubles, the extent of externalized damage generated by the industry and incurred by society and ecosystems will broaden and deepen. Current U.S. chemical regulations, notably the Toxics Substances Control Act, are grossly outdated and have failed to provide sufficient environmental protections or motivate meaningful investment in cleaner chemical technologies and safer alternatives, known collectively as green chemistry.

Given the scale of the chemical enterprise—and increasing evidence of its impact on ecosystems—a multi-pronged approach to chemicals policy is needed that enables: (1) immediate action to limit use and exposure to known hazardous substances, (2) further investigation of priority substances suspected of having ecotoxic effects, and (3) a precautionary approach that facilitates action to reduce potential risk, even where definitive evidence of cause and effect relationships is not yet established.

The new EU REACH regulation has the potential to accomplish all of these aims, and as such is the most comprehensive chemicals management regulation in the world. Its basis in the precautionary principle also makes it the most protective for health and ecosystems. Transatlantic cooperation between California and the European Union (EU), sharing information and best practices in the area of chemicals policy, could speed the development of similar policies in the U.S., beginning in California. Forging links with the EU will help California pursue substantive regulatory changes. It could provide EU policymakers a footing for strengthening REACH in subsequent negotiations and in so doing, could contribute to international sustainability efforts.

I. Introduction

Despite the enormous scale of global chemical production, decades-old U.S. chemicals regulations have proven insufficient as health and environmental protections. Their effectiveness is critical to health and ecosystems: each day, 74 billion pounds of chemical substances are produced or imported in the United States (U.S.)¹, a figure that is projected to double in two decades (Figure 1).^{2 3} All of these substances ultimately enter the earth's finite ecosystems.

Many Ecosystems that have been assumed to possess unlimited assimilative capacity, are now suffering from exposure to both legacy and "emerging" chemical contaminants.^{4 5} These effects can move beyond individual species to impact the ecosystem as a whole, illustrating the links between the chemical enterprise and global environmental problems.^{6 7}

As the environmental health sciences evolve, U.S. chemicals policy has lagged. With outdated scientific evidence and insufficient public health protections, these policies likewise fail to reflect global regulatory changes and shifting societal priorities which—from climate change to chemical hazards—are increasingly valuing precautionary decision-making.⁸

The primary U.S. statute governing chemicals, the *Toxic Substances Control Act (TSCA)*, has proved an ineffective vehicle for (1) assessing the hazards of the great majority of chemicals; (2) controlling those of greatest concern; or (3) motivating investment in the science, technology and commercial applications of cleaner chemical technologies, known collectively as green chemistry.⁹ These weaknesses have produced three chemicals policy "gaps" in the U.S.: the Data Gap, the Safety Gap, and the Technology Gap (Figure 2).¹⁰

By contrast, in the last five years the European Union (EU) has instituted sweeping policies governing chemicals and products. Most notable is the *Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)* regulation (Table 1.). REACH represents a fundamental paradigm shift in four key areas: (1) legal implementation of the precautionary principle, (2) shifting the burden of proof of safety to producers for chemicals of high concern, (3) requiring the use of safer substitutes in some cases, and (4) improving communication between chemical producers and downstream users. These changes, combined with an influx of chemical information, begin to address the lack of transparency and accountability in the chemicals market. As a result, REACH is expected to shift global markets in favor of cleaner technologies, including green chemistry.

The widening gulf between U.S. and European environmental regulation presents both an opportunity and an imperative for the U.S. to retool its approach to chemicals policy. Robust economic ties between California and the EU, including Europe's significance as an export market for California, make Europe's recent slate of chemicals regulations particularly significant for the state. Within the U.S., California has historically set the benchmark in environmental regulation. True to form, in September 2008, the state Legislature enacted two bills that take initial steps toward a more comprehensive chemicals policy, providing an opening for a two-way exchange between California and the EU.

In this paper, we will discuss the links between synthetic chemicals in the environment, the loss of global biodiversity, and the services ecosystems provide to society. We trace the origins of these issues to U.S. chemicals policies and introduce the role of green chemistry practices in minimizing the use of the most hazardous substances. In addition, we discuss the contribution of the chemical sector to climate change and the synergies between chemical contamination of the environment and the stresses posed by global warming. We describe differing approaches to chemicals policy on both sides of the Atlantic, highlighting recent regulations in the EU and exploring the potential for these to affect change in the design, production, use and disposal of chemicals and products worldwide. Finally, we propose options for cooperation between California and the EU, as these regions pursue their roles as leaders in environmental policy.

II. Biodiversity, Ecosystem Services and the Chemical Industrial System

A region's biodiversity determines many aspects of the stability, productivity and sustainability of ecosystems.^{11 12 13} Ecosystem integrity is fundamental to societal sustainability, not only through the inherent value of nature but through the provision of ecosystem services, a term that describes the value to humans of nature's "services," such as crop pollination, soil generation, pest control, waste detoxification, reduction of air pollution and water contamination, the provision of food, fiber and medicine, and the mitigation of the effects of floods, droughts and temperature extremes.^{14 15}

Ecosystems, however, are in decline worldwide. In the last century, human activities have caused between 100 and 1,000 times more species extinctions than would have been expected from natural causes, and the rate of loss is projected to increase 10-fold by 2050.^{16 17} Chronic effects of background-level exposures to synthetic chemicals and

pollutants—in combination with other stressors, such as climate change and habitat loss—can contribute to species' reproductive failure, disruption of food webs, population declines and ultimately loss of both species and genetic variety.^{18 19 20 21}

Because biodiversity contributes to human well-being in the form of ecosystem services, many of the advancements made possible by the chemical enterprise have come with a substantial societal cost.^{22 23}

Contribution of the Chemical Enterprise

Chemical substances are enormously useful to society, yet they can also be toxic and are ultimately dispersed into the earth's finite ecosystems. Despite this fact, there is a striking lack of information about the health and environmental effects of most synthetic chemicals. In fact, the toxic and ecotoxic properties of the great majority of the tens of thousands of chemicals in use in the U.S. today have never been evaluated.²⁴ Industrial chemicals and pollutants have been detected in people, and in every aquatic and terrestrial ecosystem studied.^{25 26 27}

The chemical sector has not heretofore been widely recognized for its impact on biodiversity. The chemical industry is, however, linked to some of the largest causes of biodiversity loss, including (1) pollution of soil, air, fresh water and oceans, (2) global climate change (3) urbanization and changing consumption patterns, (4) technological development, construction and mining, and (5) resource-intensive agricultural practices.²⁸ Two recent U.S. studies have highlighted the contribution of chemical contamination to threats to biodiversity in the form of habitat loss and health effects in indicator species. An assessment of western U.S. national parks found widespread chemical contamination of these ecosystems with persistent, bioaccumulative organic compounds, many of which are known to damage vegetation and wildlife, as well as health effects associated with exposure to endocrine disrupting chemicals in several species.²⁹ Similarly, a study of bird eggs from a wide range of ecosystems in both populous and remote areas in Maine found over 100 chemical contaminants, known to cause detrimental health effects in animals.³⁰ In both studies, contaminants originated from both manufacturing processes and commercial products and were traceable to both regional and remote sources.

Global Consequences

Many synthetic chemicals and pollutants are transported in air and water, contaminating areas thousands of miles from their source. This is particularly evident in polar regions, where humans, wildlife and ecosystems contain some of the highest levels of contamination measured. Most of these contaminants, such as polychlorinated biphenyls (PCBs), the pesticide dichlorodiphenyltrichloroethane (DDT), and the more recent polybrominated diphenyl ether flame retardants (PBDEs) are traceable to sources in Europe and North America.³¹

Because of their physical-chemical properties, these pollutants persist in the environment and bioconcentrate, accumulating in the food chain, with the result that highly contaminated arctic mammals are demonstrating early health effects related to chemical exposures.³² In combination with other stressors, such as climate change and habitat loss, this contamination could contribute to long-term decline of these species.³³

Such studies demonstrate that environmental contamination is an expanding and truly global issue; like greenhouse gases, synthetic chemicals do not respect national boundaries, nor are their effects confined to the areas of greatest production and use. As such, they require global solutions.

III. Linking Chemicals Policy and Ecosystem Health

Endocrine-disrupting chemicals (EDCs) are an important class of chemical contaminants for their ability to interfere with the biological signaling mechanisms governing a variety of developmental and biological functions in humans and wildlife.^{34 35} Hundreds of synthetic chemicals have been identified as EDCs, and many are environmentally persistent and bioaccumulative. They merit particular consideration, because their unique toxicological properties can produce extensive, and potentially irreversible, ecosystem damage, and because the science of endocrine disruption is not yet reflected in the tools used in U.S. environmental regulation.

Many studies have linked EDCs with population declines resulting from invertebrate imposex (masculinization or feminization), egg-shell thinning in birds and reptiles, reduced reproductive capacity in fish, and altered immune function in mammals and amphibians.³⁶ ³⁷ In some areas, entire populations of wildlife have been decimated by a single infectious agent, as has occurred, for example, with several species of frogs in California's Sierra Nevada mountains.³⁸ While the most proximate cause of this species loss was a widespread

fungal infection, it is postulated that the immune suppression associated with EDC exposure may contribute to the animals' susceptibility to infection.³⁹ The findings are especially concerning, given that amphibians are often sentinels of more widespread ecosystem damage.

EDCs are distinguished by the following properties, each of which has particular implications for chemicals policy:⁴⁰

- (1) *Dose vs. Timing*: At extraordinarily low doses, EDCs can alter an organism's reproductive capacity and cause permanent--sometimes multigenerational--changes when exposures occur during critical windows of development.^{41 42} In contrast to the long-held principle of toxicology that "the dose makes the poison," this suggests that the timing of some chemical exposures may be more relevant than the dose.⁴³ Furthermore, many EDCs act at doses well below those used in standard toxicology testing, and their nonlinear dose-response relationships frequently make extrapolations from high-dose studies inaccurate.⁴⁴

- (2) *Chronic, Mixed Exposures*: Ecosystems are typically exposed over long periods to a mixture of chemicals, some of which produce additive or even synergistic effects.^{45 46}⁴⁷ Associated risks are not accurately characterized, then, by testing that assesses chemical risks in isolation.⁴⁸

- (3) *Upstream Effects*: EDCs can produce biological changes associated with increased disease susceptibility in humans and wildlife, such as altered immune function, glucose metabolism, lipid levels or hormone activity associated with carcinogenesis.⁴⁹ These sub-clinical alterations may be "upstream indicators" of chronic diseases and may have population-level effects, even when individual effects may be insignificant.^{50 51}

- (4) *Level of Evidence and Burden of Proof*: As a precondition to action, TSCA requires EPA to prove a cause-and effect relationship—rather than establishing credible evidence of association—between chemical exposures and ecosystem effects. Yet the complexity of assessing the affects of ubiquitous and simultaneous exposures to multiple EDCs makes obtaining and evaluating this evidence—and building such a case—all but impossible.

These concepts illustrate that the traditional tools of toxicology and epidemiology, while important, are not sufficient to accurately characterize human and ecosystem exposures to, or the potential effects of, the many synthetic chemicals and pollutants that act as endocrine disruptors.^{52 53 54} The toxicological properties unique to EDCs demand a new regulatory approach—one that reflects the interconnectedness of the ecosystems on which society depends. To accomplish this, a new regulatory framework should focus on the potential for harm, even where definitive evidence of cause and effect relationships is not yet established, as described by the precautionary principle.⁵⁵

Role of Precaution

The theoretical basis for regulatory responses to scientific evidence determines much about how health-protective the regulations are. Like other environmental regulations, chemicals policies use differing standards of evidence, ranging from the most precautionary “scientific suspicion of risk”, to the most stringent “clear evidence of cause-and-effect” (See Figure 3).⁵⁶ Scientific evidence of the health and environmental effects of chemicals likewise exists along a continuum; evidence is not simply “sound” or “unsound,” as some industry representatives have argued.⁵⁷ Policy decisions therefore are made under conditions of uncertainty. As a result, decision-making tools need to be both efficient, recognizing that “perfect information” is unobtainable, and scientifically robust.

In a 1994 consensus resolution, the American Public Health Association argued that the lack of “perfect information” should not be used as a reason for delaying policy decision-making.⁵⁸ This assertion recognized the difficulty establishing proof of cause-and-effect relationships because of nonspecific health outcomes, long latency periods, subtle functional changes that require resource-intensive studies to detect, and complex interactions of variables that contribute to disease. On this basis, the resolution espoused a precautionary approach: where there are threats of serious or irreversible damage to health or the environment, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.⁵⁹

Regulation according to the precautionary principle is a response to the contingent nature of scientific knowledge and the complexity of natural systems. It aims to reduce the likelihood, extent and severity of the surprises that can arise from scientific ignorance. This is distinct from prevention, which seeks to reduce risks only from well-established hazards.⁶⁰ While TSCA requires EPA to meet the highest evidentiary standard, European chemicals policies

have codified the precautionary principle by switching from a “presumption of innocence” to a requirement that producers prove the safety and necessity of chemicals which qualify as Substances of Very High Concern (SVHC).

A Green Chemistry Alternative

Green chemistry describes two parallel processes. The first involves a scientific reorientation to improve the inherent safety of synthetic substances and prevent—rather than reduce or remediate—the impacts of chemical exposures and environmental contamination. In essence, green chemistry aims to “design out” health and environmental hazards, while reducing the consumption of energy, water and non-renewable feed-stocks, and generating fewer hazardous byproducts and waste.⁶¹ The second element of green chemistry involves a policy reorientation to identify, prioritize and take action on chemicals of concern and to speed the development of safer technologies.⁶²

Given the size of the chemical enterprise, the extent to which it is woven into the fabric of society, and the backlog of unexamined chemicals, the current reliance on resource-intensive, chemical-by-chemical risk assessments conducted by government will no longer serve. EPA will have to draw, instead, on market and regulatory tools that motivate industry investment in the design of safer chemicals and materials, based on the principles of green chemistry.

IV. Origins of the Problem: U.S. Chemicals Policy

TSCA was the U.S. response to the lack of oversight for the tens of thousands of chemicals which entered commerce before 1976.⁶³ While TSCA promised to be an important step forward, in practice, its legal and procedural requirements have largely thwarted these objectives. This is attributable to what we characterize as three overarching “Gaps” in TSCA:^{64 65 66}

Data Gap: Producers are not required to investigate and disclose sufficient information on the hazard traits of chemicals.

Safety Gap: Government does not have the information it needs to identify potential chemical hazards or risks, nor effective legal tools to mitigate them;

Technology Gap: Industry and government have invested only marginally in green chemistry research and education.

The Data Gap

With few exceptions, TSCA does not require producers either to investigate or to disclose information about chemical hazard traits. As a result, most of the 83,000 industrial chemicals in the U.S. inventory lack information on their health or environmental effects.⁶⁷ These include 62,000 chemicals that were “grandfathered” in without further review because they were already in use when TSCA was passed in 1976. Ninety-nine percent (by volume) of the highest production volume chemicals currently sold consist of these substances.⁶⁸

In addition to the lack of data on pre-1976 chemicals, a U.S. EPA audit revealed that 85% of chemical notices submitted to EPA on chemicals introduced since that time lacked information on their potential health effects, and 67% lack health or environmental data of any kind.⁶⁹

All other federal statutes combined regulate just over 1,000 chemicals and pollutants (Table 2).⁷⁰ U.S. EPA has made limited progress in closing the data gap under the voluntary High Production Volume (HPV) Chemical Challenge, which encourages producers to submit only “screening-level” information for about 3,000 chemicals produced or imported at more than one million pounds per year.^{71 72 73}

Other information on the identity of chemicals used in California is also lacking: there is no state-wide information on the volume, location or uses of chemicals or products. Likewise, there is virtually no record of their ultimate route of disposal or environmental fate.⁷⁴

The Safety Gap

In addition to insufficient data requirements, TSCA failed to grant the U.S. EPA adequate authority to investigate or regulate chemicals of concern. As a result, the Agency has been virtually unable to control even known hazards: since the passage of TSCA, EPA has issued formal rules to regulate only five chemicals (or chemical classes) of the 83,000 substances in the TSCA inventory.⁷⁵ By default, EPA has resorted to voluntary measures to encourage industry submission of data, measures that have been largely ineffectual.⁷⁶

TSCA requires EPA to prove that a chemical or product causes unreasonable harm to human health or the environment *before* the Agency can either request additional health or environmental data from industry or take protective measures.⁷⁷

In satisfying this burden of proof, EPA must meet a standard of evidence that:

- Requires health and exposure information that cannot be obtained from producers
- Often exceeds the limits of scientific knowledge
- Relies on estimates and assumptions that are easily contested
- Is limited to chemical-by-chemical assessments that can take years to complete, and yet poorly reflect actual exposures, and
- Frequently lead to substitution with another hazardous substance

TSCA effectively places EPA in a “logical paralysis:” in order to establish proof of a public health risk, agencies need health and exposure information that chemical producers are under no legal obligation to provide; to require this information, EPA must first establish proof of a public health risk.

In the absence of sufficient information, and without an effective legal framework, hazardous chemicals can enter the market and are competitive relative to potentially safer substances.

The Technology Gap

Transitioning from concept to commercial application of cleaner technologies, such as green chemistry, often requires that a company assume the risks of costly research, capital investments and leading in an emerging field. The market and regulatory weaknesses caused by the data and safety gaps, together with institutional inertia and minimal research investment, all make companies reluctant to take on these risks. This is producing a green chemistry technology gap that could place California producers at a disadvantage in this emerging global sector, while perpetuating the problems resulting from the manufacture, use, and disposal of hazardous substances.

Consequences of U.S. Policy Weaknesses

The Data, Safety and Technology Gaps engendered by TSCA have produced conditions in the U.S. chemicals market in which:

- Downstream businesses lack the information to identify hazardous chemicals;

- Government agencies do not have adequate information to systematically identify and prioritize chemical risks, nor the legal tools to efficiently mitigate known risks;
- Consumers, workers, and small-business owners do not have sufficient information to identify and use safer chemical products;
- The public bears the human and economic burden of health and environmental damage caused by chemical exposures and pollution.

While obtaining “perfect information” is not possible—or even desirable, given other societal demands—chemical prices do not currently reflect their true costs. The market therefore fails to reflect buyers’ values; given better information they might preferentially purchase less hazardous products.⁷⁸ When coupled with constraints on government’s ability to control known chemical hazards (the Safety Gap), and the lack of knowledge about toxicology or green chemistry among chemists and downstream businesses (the Technology Gap), the data-poor market makes hazardous chemicals price-competitive and the demand for green chemistry is not adequately expressed or realized.

As a result, commercial interests are motivated to protect existing chemicals, including those known to be toxic, bioaccumulative, and/or environmentally persistent.^{79 80} This is evidenced, for example, by the American Chemistry Council’s efforts to derail REACH negotiations in the EU.^{81 82 83}

California vs. the United States

To date, the U.S. has failed to ratify the Kyoto Protocol, the Convention on Biological Diversity, the Stockholm Convention on Persistent Organic Pollutants, the Basel Convention on the Control of Trans-boundary Movements of Hazardous Wastes and Their Disposal, and the Biosafety Protocol. The Bush Administration opted out of active participation in the United Nations Framework Convention on Climate Change. The EU’s Directorate General for External Relations has expressed concern over the U.S. lack of commitment to international environmental efforts, saying it “risks unwarranted and unaffordable delay in concrete action at a global level to address environmental problems.”⁸⁴

Chemicals policy reforms are already receiving attention in the Obama Administration and the current Congress. California’s restructuring of its own chemicals policy, in collaboration

with the EU, has the potential for even greater impact on the U.S. as a whole. In addition to its economic ties to Europe, California's historic role within the U.S. makes it a natural point of contact for the EU: over the last 30 years, the state has responded to complex environmental problems with policy reforms that link economic development with environmental protection.

Energy-saving policies initiated in the 1970s, for example, altered the course of California's electricity consumption: the state now uses just over 50% of the electricity per capita compared to the nation as a whole, markedly reducing greenhouse gas emissions and saving a total of \$56 billion for individuals and businesses through 2003.⁸⁵ More recently, California's success in reducing vehicle emissions has improved the state's air quality and has stimulated innovation in lower-emission technologies nationwide.⁸⁶ In addressing climate change, the state enacted legislation in 2007 that is expected to generate 89,000 new jobs in clean energy technologies by 2020.^{87 88 89}

Both the California Legislature and the Schwarzenegger Administration have now taken important steps toward leadership in chemicals policy. Seeking to drive investment in green chemistry and a shift toward a safer universe of chemicals, the California Environmental Protection Agency (Cal/EPA) launched a Green Chemistry Initiative in 2007.⁹⁰ In September, 2008, the California Legislature passed two laws (AB 1879, Feuer and SB 509, Simitian) aimed at increasing transparency and accountability in the chemicals market. Scientists and environmental advocates are now calling on the state to further shift the regulatory structure from one governed by a "presumption of innocence" to a more precautionary approach. This follows the lead of the EU and opens new opportunities for collaboration.

V. Chemicals policy: European Union

The EU has faced a similar set of environmental problems related to the production and use of synthetic chemicals, as well as to the lack of transparency or accountability in the chemicals market.⁹¹ However, Europe has responded to these problems with a slate of new policy measures that (1) establish means for managing new and existing chemicals (REACH), (2) take immediate action on chemicals of high concern (RoHS and Cosmetics Directive) and (3) set up a framework for product stewardship and producer responsibility for the full life cycle of electronic and electrical equipment (WEEE). These policies,

discussed below, are expected to shift the market to favor investment in green chemistry and other cleaner technologies.

1. The Cosmetics Directive, prohibiting the use of 1,000 known or suspected carcinogens, mutagens, or reproductive toxicants in cosmetics (2004)⁹²
2. The Waste in Electrical and Electronic Equipment (WEEE) directive, requiring producers to take back products at the end of their useful life (2005)⁹³
3. The Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) regulation, prohibiting the use of lead, cadmium, mercury, and certain flame-retardants in electronics sold in the EU⁹⁴
4. The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation, requiring that producers provide hazard and exposure information on approximately 12,000 chemicals and apply for authorization for the use of a substance of very high concern.⁹⁵

The last of these, REACH, is the most comprehensive chemicals management regulation in the world. Its basis in the precautionary principle also makes it the most progressive regulation in protecting human health and the environment from the adverse effects of hazardous chemicals.

Basic Structure of REACH

REACH requires manufacturers to register with the European Chemicals Agency (ECHA) any chemical produced or imported at more than one ton per year. Over the ten year *registration* phase, this is expected to make basic information publicly available for an estimated 30,000 chemicals. More comprehensive hazard information will be reported for a subset of approximately 12,000 substances, with data requirements tied to production volume. Much of the chemical hazard information submitted to the European Chemicals Agency (ECHA) will be accessible to residents of the EU, as well as to NGOs and foreign governments.

From the database of registered substances, EU member states will use hazard and exposure information to identify chemicals for further evaluation. Simultaneously, ECHA is

tasked with identifying—from chemicals that meet the criteria of SVHCs¹-- priority substances to subject to the Authorisation provision. ECHA has published an initial Candidate List of chemicals which will be subject to use-specific authorization, phase-out or substitution requirements. This list will grow as Member States propose chemicals to ECHA for inclusion on the Candidate List.

Impacts of REACH

The REACH regulation codifies fundamental paradigm shifts in four areas: (1) legally implementing the precautionary principle, (2) shifting the burden of proof to producers for chemicals of high concern, (3) requiring the use of safer substitutes in some cases and (4) improving communication between chemical producers and downstream users. Coupled with the directives that require product stewardship (WEEE) and restrict some hazardous substances (RoHS and the Cosmetics Directive), REACH has the potential to place human and environmental safety at the center of purchasing decisions at all levels in the chemical supply chain. This could fundamentally shift global markets in favor of cleaner technologies, including green chemistry.

Several key elements distinguish REACH from existing chemicals policies and are likely to trigger shifts toward safer alternatives. Among these are:

(1) Equivalent data requirements for new and existing chemicals: Holding existing (pre-regulation) chemicals to the same information disclosure standards as new (post-regulation) substances effectively removes disincentives to innovation and “levels the playing field”.⁹⁶

(2) Supply chain transparency: Chemical producers will be required to communicate chemical identity and hazard information to their consumers. A parallel requirement dictates that “use” information be communicated back up the supply chain from business end-users to chemical producers. This bi-directional flow of information in the supply chain is expected to facilitate hazard identification and substitution.

(3) Data requirements for chemicals in mixtures and articles: Registration is required for SVHCs included in mixtures (such as household cleaners or shampoo) and in articles (such

¹ Substances of Very High Concern (SVHC) are defined as carcinogens, mutagens or reproductive toxicants (CMRs); persistent or bioaccumulative toxicants (PBTs); very persistent and very bioaccumulative substances (vPvBs) as well as other substances of “equivalent concern,” such as endocrine disruptors.

as building materials, clothing, furniture or cars), based on total volume produced or imported, percentage of the article by weight, and hazard to humans or the environment. This will likely make information available on the chemical constituents of many products.

(4) Prioritizing hazardous substances: The process of identifying and prioritizing chemicals of concern is embodied in the Evaluation and Authorisation provisions of REACH. While the tasks for ECHA and the Member States are formidable, for the first time, there is a process which defines criteria for hazardous substances and places the burden of proof of their safety on manufacturers. In addition, anecdotal evidence suggests that publication of the Candidate List is triggering some companies to eliminate known hazardous chemicals from their portfolios in advance of regulation.

Potential Limitations of REACH

In both its scope and its basis in the precautionary principle, REACH is truly a landmark regulation. Decisions made during the implementation phase, however, will largely determine its success.

(1) Data requirements do not apply to all chemicals in commerce—Chemicals produced or imported in quantities less than 1 ton/year (an estimated 70,000 substances) will not be subject to registration, the most basic requirement under REACH. Only rudimentary data are required for substances produced or imported at a volume of 1-10 tons/year (approximately 17,500 substances, or 60% of those that are subject to registration).

(2) Limited dossier review and validation—An electronic check will confirm the completeness of all dossiers submitted by chemical producers; however, only 5% of dossiers in each tonnage band will be evaluated for compliance, a more thorough review of the data's relevance and accuracy. While the burden of providing information on targeted chemicals has been shifted to producers, the government will face an enormous task of evaluating the data quality.

(3) Limited Candidate List—To nominate SVHCs for the Candidate List Member States must prepare an extensive dossier for each chemical. That burden, combined with ECHA's limited capacity to review the dossiers produced an initial Candidate List of just 14 substances.⁹⁷ Meanwhile, the Swedish NGO, International Chemicals Secretariat (ChemSec) generated a

list of 267 substances that meet the criteria for SVHCs stipulated in REACH, suggesting that they would all be suitable for nomination for the Candidate List.⁹⁸

(4) Thresholds for regulating substances in articles— Chemicals in articles must only be registered if they make up more than 0.1% of the article's total weight, a process that may shield many potentially hazardous substances from reporting.⁹⁹

(5) Limited substitution requirements—Chemicals classified as dangerous by the EU,¹⁰⁰ and those placed on the Candidate List may be subject to mandatory substitution. However, if manufacturers can prove they can achieve “adequate control” for specific uses, companies may gain authorization for their continued use. Many substances, such as EDCs, have no valid “safe threshold” of exposure.¹⁰¹

It remains to be seen how each of these issues is resolved as REACH is implemented and enforced over the coming decade.

VI. Policy implications

Global ecosystem contamination, biodiversity loss and threats to ecosystem services reflect the impacts of chemical and product management around the world.

Implementation of the REACH regulation has informed and bolstered California's chemicals policy reform; it has provided model methods and structures, and it has forced change within a historically intransigent U.S. chemical enterprise. By controlling access to European markets, REACH sets what may become a *de facto* global standard for information disclosure. Additionally, its passage has introduced immediate economic pressures and an element of inevitability into California chemicals policy discussions.

Transatlantic learning to date

As important economic partners, and with similar health and environmental priorities, California and the EU have a history of collaboration on international issues. The EU has publicly recognized California as a policy leader and innovator in the US, particularly on environmental issues.¹⁰² During a recent visit to California, EU Ambassador to the U.S. John Bruton addressed members of the state legislature and signed a Memorandum of Understanding with the Chancellor of the University of California, Berkeley, agreeing to support regulatory cooperation between California and the EU in areas such as biodiversity, climate change, green chemistry, and waste management.

In the 2004 Dromoland Summit, the EU and the U.S. launched a joint Initiative to Enhance Transatlantic Economic Integration and Growth, committing to regulatory cooperation and technological innovation to “expand economic opportunity, promote prosperity, and maintain the health and safety of our peoples.”¹⁰³ California can set the bar for U.S. follow-through in participation in this Initiative.

The state’s strong economic ties with Europe make engagement with these policies unavoidable: multinational businesses must comply with EU regulations or risk losing critical markets. Similarly, regions with more lenient standards than the EU face the prospect of becoming markets for hazardous goods prohibited in Europe.¹⁰⁴

Trade links between California and the EU are robust: trade with and investment by the EU earns California \$63 billion annually and supports over one million jobs in the state.¹⁰⁵ As an export market for California, the EU earns the state \$28 billion annually, making it twice as large as Japan and China combined, and California is the top U.S. exporting state to Europe.¹⁰⁶ Thus, Europe’s recent slate of policies addressing chemicals and products has significant implications for California’s businesses. Just two classes of merchandise that will be subject to new EU environmental regulations, chemicals and electronics, totaled 46% of California’s exports to the EU, earning the state \$13 billion in 2008.¹⁰⁷

The potential for continued transatlantic learning

With its ongoing Green Chemistry Initiative and recent passage into law of AB 1879 and SB 509, California has initiated the development a more comprehensive approach to chemicals policy. This is already producing a host of technical questions that will require new kinds of expertise, much of which is being developed in the EU. California’s effort to lead the U.S. in chemicals policy would be bolstered by cooperation with the EU, through technical consultation, strategy development, and data exchanges.

Likewise, public and environmental health advocates in the EU stand to benefit if California, in its own chemicals policy, addresses limitations of REACH. California has the opportunity to respond to the pressure created by both internal problems (health, environmental and economic consequences of the chemical enterprise) and external forces (EU requirements and global market demand). Done well, this has the potential to 1) fuel global demand for safer substances, increasing the incentive for innovation in green chemistry, 2) contribute to

improvements in human health, resource conservation and environmental protection, and 3) shift the U.S. into a position of greater collaboration in international sustainability efforts.

Mechanisms to advance transatlantic learning

California and the EU should pursue cooperation in the following ways:

Share Information

(1) *Inter-agency Memoranda of Understanding (MOU)*: California's new chemicals policy bill, AB 1879, authorizes state officials to draw on information available to other governments. Using this vehicle, the California Environmental Protection Agency's (Cal/EPA) Department of Toxic Substances Control (DTSC) is pursuing MOU with Competent Authorities in Member States. It should do the same with the European Union Chemicals Agency (ECHA) to ensure California's access to chemical information submitted under REACH. As California companies submit information to EU authorities, it will become increasingly untenable for those companies to withhold such data from Cal/EPA, U.S. EPA and the public. Although U.S. EPA has previously requested similar data from chemical producers, it lacks the legal authority to require disclosure, with the result that producers have submitted only limited information.

(2) *Research collaborations*: Both California and the EU are attempting to fill existing gaps in information about health and environmental effects of chemicals. Increasing international collaboration on the research questions asked—and data generated— by publicly funded research projects could eliminate redundancies and significantly speed these efforts.

(3) *Biomonitoring*: While some Member States have significant information from decades-old biomonitoring research, in the last year, both California and the EU have initiated new biomonitoring programs.¹⁰⁸ Data generated by these programs on human exposure to synthetic chemicals and pollutants, will inform the process of prioritizing chemicals of concern. Sharing data will increase understanding of regional variations in chemical exposure and disease.

(4) *Connect to non-governmental organizations (NGOs)*: European NGOs were closely involved in all aspects of developing the REACH regulation. California can tap into their expertise. For example, among information available to both governments is the so-called "SIN List 1.0"—the 267 substances identified by the Swedish NGO, ChemSec, as substances

of very high concern, or SVHC. Because ChemSec identified these chemicals using the same criteria stipulated under REACH, this list can help both ECHA and DTSC identify and prioritize chemicals for immediate action or further investigation.

REACH also permits external proposals for chemicals for the Candidate List; California agencies, researchers or public interest groups could partner with Member States and NGOs to recommend high risk chemicals that should be subject to the authorization process.

Share Best Practices

Implementing a chemicals policy such as REACH requires regulatory agencies as well as affected business to address a host of technical questions. ECHA and DTSC will have to address distinct issues relevant to implementing their own regulations. The two agencies should establish a means of sharing best practices on such issues as:

- (1) Developing chemical and product life-cycle assessment tools that minimize risk-shifting among environmental media while remaining efficient and widely applicable.
- (2) Developing methods of assessing alternatives to chemicals of concern, addressing the problems inherent in weighing relative hazards, evaluating emerging science, and making decisions under conditions of uncertainty.
- (3) Performing cost-benefit analyses for regulations that encompass the costs to society incurred from environmental harm and loss of ecosystem services.
- (4) Providing reasonable protection for confidential business information, while ensuring that key information such as chemical identity and hazard traits remains public.
- (5) Building an appropriate information technology (IT) infrastructure.

Contribute to the International Effort

Harmonize regulations: The implementation of REACH, California's new laws, and the prospect of impending TSCA reform at the U.S. federal level, risks producing a patchwork of chemical regulations, thereby creating markets for substandard goods as well as bulky compliance issues for multinational companies. The efficiencies that can occur with harmonization of regulations, where appropriate, will benefit the public, businesses, industry and government.

Join the international environmental community: California should encourage the U.S. government to support a multinational environmental agenda by such actions as ratifying the Stockholm Convention on Persistent Organic Pollutants, the Basel Convention on the Control of Trans-boundary Movements of Hazardous Wastes and Their Disposal, and the Convention on Biological Diversity.

VII Conclusion

Synthetic chemicals and pollutants, including many EDCs, are now ubiquitous environmental contaminants, and evidence points to their association with declining biodiversity and the provision of ecosystem services.

The EU has assumed global leadership—through enacting the REACH regulation—in environmental stewardship and regulatory stimulus toward the design, production, and use of safer chemicals and products. California has enacted two new green chemistry laws, but how they are implemented will determine whether California joins the EU, or cedes to others both market share and the opportunity for implementing critical environmental protections.

While the U.S. has largely lost its stature as a global leader in environmental policies, California has a record of tackling complex environmental issues with policy reforms that link economic development with improvements in human health and ecosystem protection. The state's emerging chemicals policy will need to adopt a precautionary approach that reflects the realities of increasingly vulnerable ecosystems, shifting societal priorities, and advances in the environmental health sciences.

The contrast between existing federal chemicals policies and the new regulatory approach adopted by the EU offers an unprecedented opportunity for a two-way exchange between California and the EU. Forging links with the EU will facilitate California's process and could provide EU policymakers a footing for strengthening REACH in subsequent negotiations. Transatlantic cooperation could thus speed the development of comprehensive new chemicals policies, and California has the chance to play a leading role in addressing critical global environmental problems.

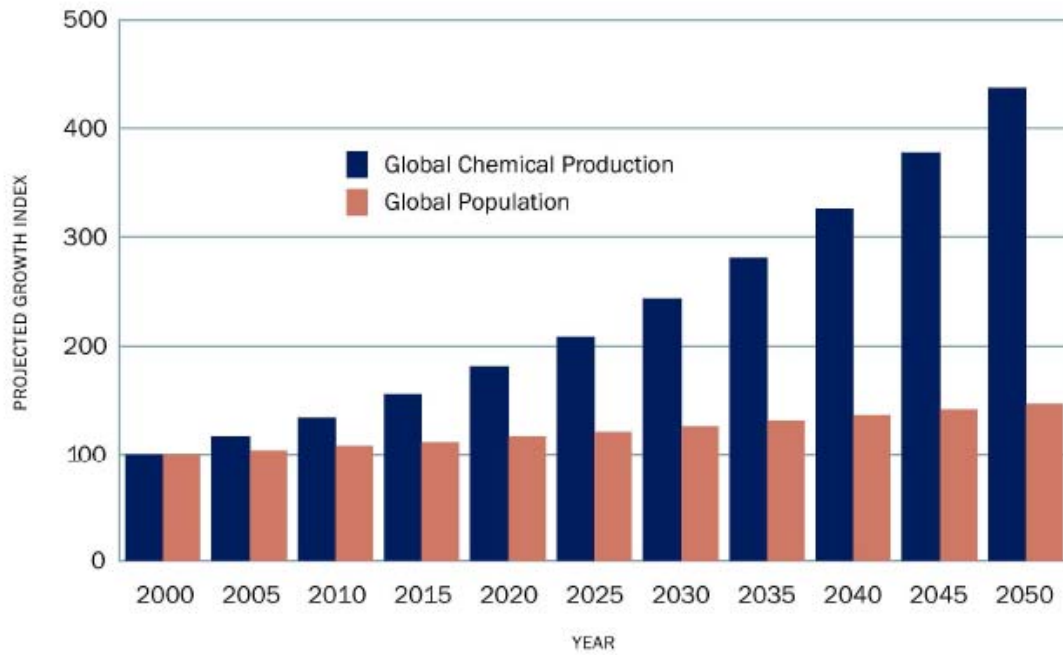
Table 1. Core Distinctions between U.S. and EU Chemicals Policy

Policy Area	Treatment by TSCA	Treatment by REACH
Burden of proof & level of evidence	Government agencies bear high burden of proof of harm before restricting use.	“No data, no market”: Producers supply hazard information for over 10,000 chemicals
Existing chemicals (pre-regulation)	Existing chemicals “grandfathered” in and assumed safe	All substances subject to the same volume-based data requirements
New chemicals (post-regulation)	Pre-manufacture notification, but no minimum data set	Same requirements as for existing chemicals
Prioritizing hazardous chemicals	No screening criteria required; regulation is on a chemical-by-chemical basis	Select SVHCs are subject to use-by-use authorization by ECHA
Supply chain transparency	No requirements	Two-way information flow in the supply chain
Information access	No general disclosure; extensive CBI claims permitted	More public access required; clear designation of CBI with some limits

Table 2. While TSCA applies to tens of thousands of substances, only 1,134 chemicals and pollutants are listed by other U.S. statutes.¹⁰⁹

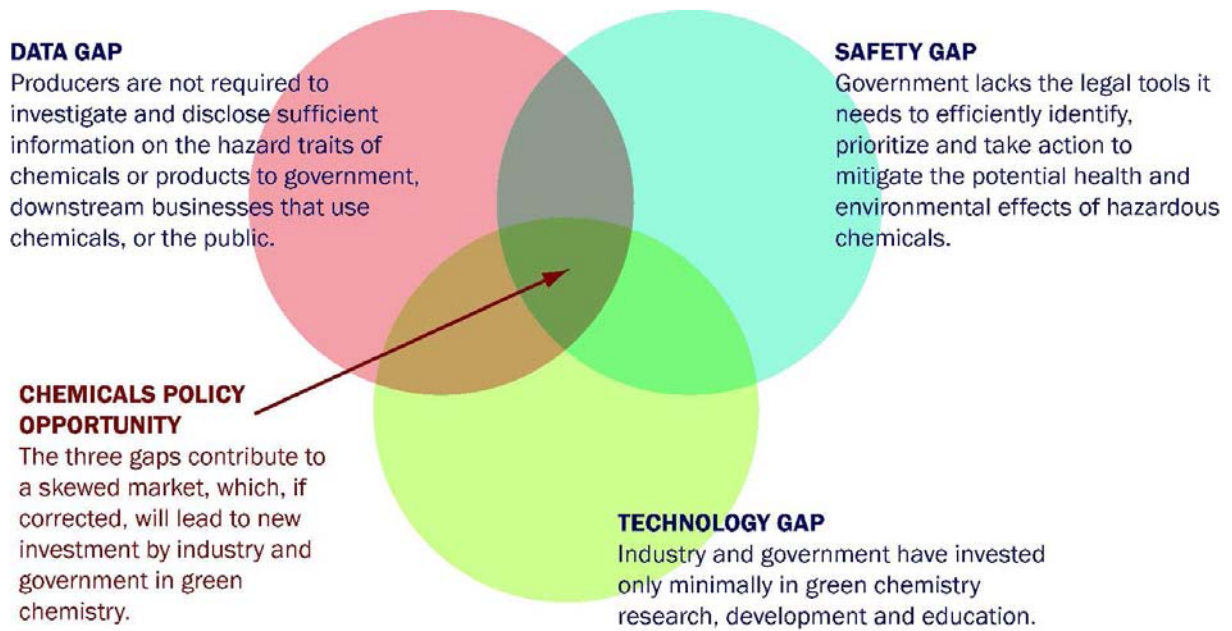
Federal statute	Number of chemicals
Clean Water Act (CWA)	148
Resource Conservation and Recovery Act (RCRA)	502
Clean Air Act (CAA)	189
Occupational Safety and Health Act (OSH Act)	453
Emergency Planning and Community Right-to-Know Act; Toxics Release Inventory (EPCRA–TRI)	600

Figure 1. Projected global chemical production relative to population growth



Global chemical production is projected to grow at a rate of 3% per year, rapidly outpacing the rate of global population growth, estimated at 0.77% per year. On this trajectory, chemical production will double by 2024, indexed to 2000.

Figure 2. U.S. Chemicals Policy Gaps



The three gaps in U.S. chemicals policy: Data Gap, Safety Gap and Technology Gap. Policy measures that address the gaps will promote sustainable innovation in the chemical enterprise while improving human health and the environment.

Figure 3. Spectrum of levels of evidence as the basis for decision-making



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